

Amendment
Serial No. 10/612,784
Docket No. ORW01-GN004

REMARKS

Introductory Comments

Claims 1-90 are pending in the present application. Claims 17, 18, 38, 39, 80, 81, 89, and 90 have been withdrawn in light of the previous restriction requirement. Claims 1, 27, 54, 73, and 82 have been amended. Claims 91-108 have been cancelled. Reconsideration of the application is respectfully requested.

Instant Office Action

Restriction Requirement

The July 21 Office action indicated that pending claims, 1-108, were subject to a restriction or election requirement. The Office action indicated that Applicant was required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits.

As indicated on Page 2 of the July 21 Office action, it was alleged that the application contained claims directed to two patentably distinct inventions: (1) Species I, corresponding to claims 1-90, drawn to a restraining device, classified in class 623, subclass 11.11; and (2) Species II, corresponding to claims 91-108, drawn to a method of providing temporary stability to a prosthetic hip, classified in class 623, subclass 22.24. Applicant elected in writing to prosecute claims 1-90, corresponding to Species I, drawn to a restraining device, **without traverse**.

The July 21 Office action also alleged that the application contained claims directed to three patentably distinct subspecies: (1) Subspecies I, corresponding to a scar tissue promoting agent; (2) Subspecies II, corresponding to a clotting agent; and (3) Subspecies III, corresponding to an antibacterial agent. Applicant elected in writing to prosecute claims 1-90, corresponding to Subspecies I, drawn to a scar tissue promoting agent, **with traverse**.

The instant September 30 Office action continues to maintain that Subspecies II and Subspecies III are patentably distinct from Subspecies I. The Examiner has

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withdrawn the claims reading on Subspecies II and Subspecies III, however, it is acknowledged that if the intervening claims are found patentable, Applicant will be entitled to a notice of allowance encompassing Subspecies II and Subspecies III.

Information Disclosure Statement

The September 30 Office action alleges that the information disclosure statements filed by the Applicant do not comply with 37 C.F.R. §1.98(a)(3). This allegation is in error. Applicant explicitly stated that the relevance of these references derives from the International Search Report issued by the International Searching Authority in the counterpart PCT application to the instant application. It is respectfully submitted that this statement fully complies with the requirements of 37 C.F.R. §1.98(a)(3).

A supplemental information disclosure statement is filed herewith that includes a copy of the international search report that was also filed with the original information disclosure statement.

It is respectfully requested that the Examiner consider the references cited in all of the information disclosure statements filed by Applicant.

Objection to the Drawings

The drawings are objected to as allegedly being deficient in not showing that the constraining augments are adapted to be fastened to the "acetabular cavity within a hip bone" or "positioned about a femoral member." The objection to the drawings is traversed.

One skilled in the art looking at the drawings would readily understand that the means shown for fastening the constraining augments in FIG. 4 could equally be applied to a "acetabular cavity within a hip bone." No magic language in the specification is required for one skilled in the art to make this connection. More specifically, the Office action has failed to direct Applicant's attention to a particular reference or other objective evidence that would tend to cast doubt upon Applicant's assertion that one skilled in the art would understand the means for fastening the constraining device shown in FIG. 4 as applicable to fastening the constraining augment to a patient's native bone. Along these

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same lines, positioning multiple augments as shown in FIG. 4, would necessarily result in augments being "positioned about a femoral member" as the femoral member is represented by the femoral head 18. Bases for the limitation that the augments may be mounted to a patient's native bone can be found at [0010] and [0012]. Therefore, Applicant respectfully submits that the objection to the drawings is without merit and should be withdrawn.

35 U.S.C. §112, Second Paragraph Rejections

Claims 1-26 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as his invention. More specifically, it is alleged that the scope of claims 1-26 is indefinite as it is uncertain whether a prosthetic device or a constraining device is being claimed. This ground of rejection has been overcome by the amendment to claim 1, and is moot for claims 17 and 18 in light of the Examiner's withdrawal of these claims.

Claims 1-16 and 19-26 are directed to a prosthetic device operative as a temporary constraining device. It is respectfully submitted that whether the device is prefaced with "prosthetic" or "constraining," the implication remains the same. Thus, the use of "prosthetic" and "constraining" are simply two analogous adjectives in the preamble that preface to the same noun. In light of the apparent confusion generated by the concurrent use of these adjectives, Applicant has replaced the occurrence of "constraining device" with "prosthetic device."

Reconsideration and withdrawal of the rejections of record for claims 1-16 and 19-26 are respectfully requested.

35 U.S.C. §112, First Paragraph Rejections

Claims 54-90 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. This ground of rejection is

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respectfully traversed as the application fully supports the limitations recited within claims 54-90.

The Office action identifies claims 54 and 82 as allegedly being the most extreme examples of the specification failing to support certain claim limitations. Claims 54 and 82 generally recite a prosthetic augment that may be mounted to a patient's bone to stabilize the engagement between a prosthetic component and a patient's native bone. An example of such a combination would be the interaction between a femoral prosthetic device and a patient's native hip bone (acetabulum), encompassing the patient's native acetabular cup. The specification identifies such an exemplary usage at paragraphs [0010] and [0012], as well as the fact that the originally filed claims provide their own written description support (see *In re Koller*, 613 F.2d 819 (C.C.P.A. 1980)). In light of this apparent oversight, reconsideration and withdrawal of the rejections of record for claims 54-90 are respectfully requested.

35 U.S.C. §102 Rejections

Claims 1-16, 19-37, 40-79, and 82-88 stand rejected under 35 U.S.C. §102(c) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0024471 to Ferree ("Ferree"). This ground of rejection with respect to claims 1-16, 19-37, 40-53, 73-79, and 82-88 has been overcome by the amendments to claims 1, 27, 73, and 82. This ground of rejection with respect to claims 54-72 is respectfully traversed.

First, the Office action incorrectly asserts that Applicant's use of "comprising" in the claims obviates the "semiannular" limitation and allows for an interpretation of the augment 120 of Ferree as being "semiannular." This assertion is incorrect. The case law in this area is clear and certainly does not support the Examiner's current position.

When a patent claim uses the word "comprising" as its transitional phrase, the use of "comprising" creates a presumption that the body of the claim is open. In the parlance of patent law, the transition "comprising" creates a presumption that the recited elements are only a part of the

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device, that the claim does not exclude additional, unrecited elements.
(emphasis added) (emphasis)

Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc., 246 F.3d 1336, 1348 (Fed. Cir. 2001). The case law provides no basis for the position recited in the Office action that certain claim elements can be ignored because of the use of "comprising." If the Examiner's interpretation of the law were adopted, a claim limitation reciting "discontinuous" would be anticipated by something that was continuous. The component 120 of Ferree is not semiannular; it is annular. Therefore, Ferree fails to anticipate claims 1-53.

The Examiner's interpretation of the component 120 of Ferree being semiannular is also belied by the statement on page 6 of the Office action, "[h]owever, Ferree shows the augment as being annular and one piece." The component 120 of Ferree is annular, not semiannular. An interpretation to the contrary ignores the distinction between semiannular and annular. Thus, claims 1-53 are distinguishable and allowable over Ferree.

Claims 1, 27, 73, and 82 have been amended to clarify that the claimed device allows angular adjustment between the femoral component and the acetabular component. Ferree fails to disclose a constraining device that allows for angular adjustment. Ferree appears to disclose a resorbable component entirely circumferentially disposed around the femoral component, approximate the stem and prosthetic ball. Ferree is silent as to what the resorbable material is mounted to, nor how the resorbable material is mounted to certain components of the prosthetic assembly. Moreover, FIG. 11D of Ferree conclusively shows that angular movement between the socket and ball components is disallowed in all 360 degrees about the prosthetic cup. The conclusion is further confirmed by [0081] of Ferree that states,

A resorbable component 120 is located between component 118 and rod component 114 to restrict motion between the acetabular and femoral components of device 112 until resorbable component 120 disappears, allowing time for bone ingrowth to firmly take hold.

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Thus, it is clear that the resorbable component 120 of Ferree does not allow angular adjustment between the femoral component and the acetabular component. Therefore, claims 1-16, 19-37, 40-53, 73-79, and 82-88 are clearly distinguishable over Ferree.

Finally, the Office action alleges that it is inherent to have multiple prosthetics 112, therefore, having a plurality of constraining augments 120. This conclusion is not reasonable in light of a proper interpretation of the limitations of claims 54-72. Claims 54-72 are directed to a prosthetic constraining kit for implantation in proximity to a hip joint, comprising a plurality of compression constraining augments being adapted to be individually fastened on at least one of an acetabular prosthesis and about an acetabular cavity within a hip bone. Ferree, instead of disclosing a plurality of compression constraining augments that can be concurrently mounted on at least one of an acetabular prosthesis and about an acetabular cavity within a hip bone, discloses a single, circumferential component 120. The disclosure of Ferree is one type of art (providing no flexibility or range of movement) the instant invention was intended to overcome. Moreover, Ferree does not disclose that the component 120 is separable from the prosthetic structures, and even if it was, would not be combinable with other circumferential components 120 to comprise a "kit." Therefore, Ferree does not disclose each and every one of the limitations of claims 54-72.

Reconsideration and withdrawal of the rejections of record in light of Ferree for claims 1-16, 19-37, 40-79, and 82-88 are respectfully requested.

Claims 1-16, 19-37, 40-79, and 82-88 stand rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 6,228,122 to McGann ("McGann"). This ground of rejection with respect to claims 1-16, 19-37, 40-53, 73-79 has been overcome by the amendments to claims 1, 27, 54, 73, and 82.

Claims 1, 27, 54, 73, and 82 have been amended to clarify that the claimed device is compressive in nature to inhibit dislocation and maintain engagement between the respective moving components, whether the components are native bone, other tissue, or prosthetic devices. In direct contrast, the devices of McGann are clearly in tension like a

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rubber band to restrain movement between engaged components. Moreover, no teaching of McGann provides any indication that the bands maintain the proper engagement of components while the bands are in compression. Therefore, the amendments to claims 1, 27, 54, 73, and 82 clearly distinguish the structures of McGann and are therefore in condition for allowance, as well as the claims that depend therefrom.

Reconsideration and withdrawal of the rejections of record for claims 1-16, 19-37, 40-79, and 82-88 are respectfully requested.

35 U.S.C. §103 Rejections

Claims 1-16, 19-37, 40-79, and 82-88 stand rejected under 35 U.S.C. §102(e) as allegedly being obvious over U.S. Patent Application Publication No. 2004/0024471 to Ferree ("Ferree"), in view of U.S. Patent No. 4,004,300 to English ("English"). This ground of rejection with respect to claims 1-16, 19-37, 40-79, and 82-88 is respectfully traversed.

The Office action has mischaracterized the components disclosed by of the respective references, Ferree and English, and thus the allegation that claims 1-16, 19-37, 40-79, and 82-88 are unpatentable in view of these references is without merit when properly understood. The Office action characterizes the component 120 of Ferree as an augment, while also characterizing the shell halves 29, 30 of English as augments. These respective elements serve entirely different purposes and therefore are not equivalents and thus cannot be both considered "augments" for purposes of determining patentability of Applicant's claims.

To render obvious claims 1-16, 19-37, 40-79, and 82-88, Ferree and English must:

- (1) provide some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference;
- (2) provide a reasonable expectation of success; and (3) teach or suggest all the claim limitations. M.P.E.P. § 2143. The Office action fails to meet at least the first two of these requirements with respect to the allegation that Applicants' claims 1-16, 19-37, 40-79, and 82-88 are obvious in light of Ferree combined with English.

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First, neither Ferree nor English provides any suggestion or motivation to combine these references with one another. In fact, the references on their face are not readily combinable because the disclosures teach away from the alleged combination articulated in the Office action. For example, the Office action alleges that the resorbable component 120 of Ferree is an equivalent in structure to the shell halves 29, 30 of English. This allegation ignores the purpose and intended lifespan of the respective components.

One skilled in the art would not combine these references, most notably because the teachings of English indicate that the shell halves 29, 30 give "long and useful service," in contrast to the resorbable component 120 of Ferree that is temporary and goes away after a short period of time. English expects that the shell halves 29, 30 will stay intact and not degrade, otherwise reconstructive surgery would be required after only a few months to replace the acetabular cup. In other words, the shell halves 29, 30 of English are never intended to be reabsorbed, unlike the component 120 of Ferree.

Ferree's resorbable component 120 is utilized to temporarily restrict all movement between the femoral and acetabular components, but at no time is the component 120 used as an acetabular cup or insert. In contrast, the shell halves 29, 30 of English form the acetabular cup that receives the femoral head to allow rotational and angular movement of the head with respect to the cup. In sum, the component 120 of Ferree and the shell halves 29, 30 of English have completely different purposes and are specifically designed to have vastly different operating lives that negate any alleged combination.

Second, neither Ferree nor English provides a reasonable expectation of success. As discussed above, allowing the shell halves 29, 30 of English to be fabricated from a resorbable material would require frequent reconstructive surgery to replace the acetabular cup. This is certainly not reasonable to those skilled in the art, nor those who would be recipients of such surgical implants. It is illogical to assert that more frequent

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surgical procedures would be preferred over longer term solutions, which is precisely the case by alleging that English is combinable with Ferree.

In sum, one skilled in the art would not be motivated to combine the disclosures of Ferree and English to allegedly render obvious claims 1-16, 19-37, 40-79, and 82-88. Reconsideration and withdrawal of the rejections of record for claims 1-16, 19-37, 40-79, and 82-88 are respectfully requested.

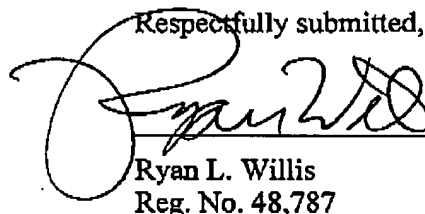
Conclusion

In light of the foregoing, it is respectfully submitted that claims 1-90, now pending, are patentably distinct from the references cited and are in condition for allowance. Reconsideration and withdrawal of the rejections of record are respectfully requested.

The Commissioner for Patents is hereby authorized to charge any additional fees that may be required by this paper, or to credit any overpayment to Deposit Account 50-3072.

In the event that the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number indicated below.

Respectfully submitted,



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